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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,618	09/25/2003	Stephen T. Flock	D6476	6784

7590

09/01/2004

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EXAMINER

HAYES, MICHAEL J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,618	FLOCK ET AL.	
	Examiner	Art Unit	
	Michael J. Hayes	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 02 August 2004.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-69 is/are pending in the application.

4a) Of the above claim(s) 7 33 38-42 45-49 52-59 63-69 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-6,8-32,34-37,43,44,50,51 and 60-62 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 3/08/04.

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-6, 8-32, 34-37, 43, 44, 50, 51, and 60-62 in the reply filed on 8/02/04 is acknowledged.
2. Claims 7, 33, 38-42, 45-49, 52-59, and 63-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/02/04.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling how a material, such as polypyrrol, filings, or Nitinol functions as a means for driving an applicator.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 8, 13, 14,-16, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by HEYMAN (US Patent No. 4,331,422). Heyman discloses an applicator, piezoelectric means to drive applicator, abrasive in water lubricant to alter tissue. The device is capable of use on stratum coreum, bone, and capable of delivering a pharmaceutical.
3. Claims 1-6, 8, 13-18, 20-26, 30, 31, 34, 35, 36, 43, 44, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by WEAVER et al. (Pub. No. 2002/0065533 A1). Weaver discloses a device for ablating tissue and delivering pharmaceuticals using aluminum oxide, ice, or a pharmaceutical as the abrasive, providing an operatively connected collection means, and monitoring optical reflectance of the tissue. See particularly ¶s 19, 34, 47, 58, 59, 104-112, 115, and 128.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 27, 28, 32, 37, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER as applied to claims 26, 31, 36, and 1 above, and further in view of EGGERS (US Patent No. 6,066,134). Weaver discloses the claimed invention except for monitoring feedback using a heartbeat with the device, crystallized pharmaceutical, absorptive cotton as collector, and monitoring feedback about a thermal property of the tissue. Eggers teaches monitoring feedback using a heartbeat and a thermal property of the tissue to perform a safe ablation procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eggers in the device of Weaver to increase the safety of the ablation procedure for better patient outcome. The use of crystallized pharmaceuticals in drug delivery and absorptive cotton in medical collection of liquids is notoriously well known in the art of drug delivery and sampling.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER as applied to claim 20 above, and further in view of UNGER (US Patent No. 6,416,740). Weaver discloses the claimed invention except for a reservoir with a permeable membrane to release the pharmaceutical. Unger teaches the use of a permeable membrane to release the pharmaceutical in a patch applied to the skin of a patient (see 69:11-14). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Unger in the device of Weaver in order to provide a convenient patch for drug delivery through the skin.

7. Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER as applied to claim 60 above, and further in view of MELBOUCI et al. (US Patent No. 6,562,090). Weaver discloses the claimed invention except for using a lubricant of water and glycerol with the abrasive. Melbouci teaches using water and glycerol with a lubricant to

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provide a stabilized suspension of abrasive in lubricant (see claim 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Melbouci in the device of Weaver in order to facilitate the use of the abrasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
28 August 2004



**MICHAEL J. HAYES
PRIMARY EXAMINER**